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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 10/804,845

Filing Date: 03/19/2004

Applicants: Robert Harris et al.

Entitled: IMMUNOMODULATION BY A THERAPEUTIC MEDICATION INTENDED FOR TREATMENT OF DIABETES AND PREVENTION OF AUTOIMMUNE DIABETES

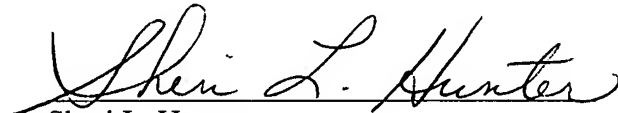


Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.18(A)

Date of Deposit: January 5, 2006

I hereby certify that this correspondence is being deposited with the US. Postal Service with sufficient postage as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Sheri L. Hunter

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.97-1.98

As authorized and encouraged under 37 CFR §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05 (b), Applicants submit herewith certain patent references, publications and/or other information which the Patent and Trademark Office may wish to consider in examining the above-

identified patent application. The references and information are listed below and on attached Form PTO-1449.

U.S. PATENTS

| U.S. PATENT NUMBER | INVENTOR(S) |
|--------------------|-------------|
| 4,473,495 | Patterson |

U.S. PATENT APPLICATIONS

| U.S. PUBLICATION NUMBER | INVENTOR(S) |
|-------------------------|---------------|
| US 2002/0090357 A1 | Barrat et al. |

FOREIGN DOCUMENTS

| COUNTRY | PATENT NO./PUBLICATION NO. | INVENTOR(S) |
|---------------------------------|----------------------------|-------------|
| PCT International Search Report | PCT/IB2005/002124 | Robertson |
| PCT | WO 2004/035084 A2 | Harris |

OTHER DOCUMENTS

1. Banga, J. P. et al., Modulation of Antigen Presentation by Autoreactive B Cell Clones Specific for GAD65 from a type I Diabetic Patient, Clinical and Experimental Immunology, Vol. 135, No. 1, January, 2004, pp. 74-84.
2. Chen Shiow-Ling et al., Responses of NOD Congenic Mice to a Glutamic Acid Decarboxylase-derived Peptide, Journal of Autoimmunity, Vol. 7, No. 5, 1994, pp. 635-641.
3. DMCCAD: GAD in Metabolic & Neurologic Disease, http://www.diamyd.com/docs/pdf/GAD_IN_METABOLIC_PD, June, 2003.

4. Patent Abstracts of Japan, Vol. 1997, No. 12, 12/25/97, JP 09 2200092 A.
5. Endl Josef et al., Identification of Naturally Processed T Cell Epitopes from Glutamic Acide Decarboxylase Presented in the Context of HLA-DR Alleles by T Lymphocytes of Recent Onset IDDM Patients, Journal of Clinical Investigation, Vol. 99, No. 10, 1997, pp. 2405-2415.
6. Tian Jide et al., T Cell Cross-Reactivity Between Coxsackievirus and Glutamate Decarboxylase is Associated with a Murine Diabetes Susceptibility Allele, Journal of Experimental Medicine, Vol. 180, No. 5, 1994, pp. 1979-1984.
7. PCT International Search Report, PCT/IB2005/002135, 08/11/2005.
8. Press Release: Diamyd increases C-peptide levels in diabetes patients with GAD antibodies, online 11/24/2003, http://222.diamyd.com/docs/PressClip.a.spx?PageID=10&LangID=2&ClipID=210&sm+b_b, pp. 1-55.
9. Diamyd: Halvarssrapport for Diamyd Medical AB, online 05/02/2000, pp. 1-5, <http://di.se/Avdelningar/pressreleaseShow.aspx?pressSeqNo=996&pressCp=1&smallscreen+0&>>.
10. Ramiya, V. K. et al., Immunization Therapies in the Prevention of Diabetes, Journal of Autoimmunity, London, GB, Vol. 10, 1997, pages 287-292, XP002918457 abstract.
11. Christgau, S. et al., Membrane Anchoring of the Autoantigen GAD65 to Microvesicles in Pancreatic Beta-Cells by Palmitoylation in the NH₂-Terminal Domain, Journal of Cell Biology, Rockefeller University Press, New York, US, US Vol. 118, No. 2, July 1, 1992, abstract.

12. Falornia et al., US 6 093 396 A, July 25, 2000 abstract.
13. Petersen et al., Neonatal Tolerization with Glutamic Acid Decarboxylase but not with Bovine Serum Albumin Delays the Onset of Diabetes in NOD Mice, Diabetes, Vol. 43, No. 12, December, 1994, pp. 1478-1484.
14. Zimmet et al., Latent Autoimmune Diabetic Mellitus in Adults (LADA): The Role of Antibodies to Glutamic Acid Decarboxylase in Diagnosis and Prediction of Insulin Dependency, Diabetic Medicine, Vol. 11, 1994, pp. 299-303.
15. Elliott, J. F. et al., Immunization with the Larger Isoform of Mouse Glutamic Acid Decarboxylase (GAD67) Prevents Autoimmune Diabetes in NOD Mice, Diabetes, New York, NY, US, Vol. 43, No. 12, 12/01/1994, pp. 1494-1499.
16. Tisch, R. et al., Antigen-specific Mediated Suppression of Beta Cell Autoimmunity by Plasmid DNA Vaccination, Journal of Immunology, The Williams and Wilkins Co., Baltimore, US, Vol. 166, No. 3, 02/01/2001., pp. 2122-2132.

Copies of the non-patent references are attached. These references are being disclosed for the express purpose of providing the Patent and Trademark Office with ample opportunity to evaluate the same and arrive at an independent assessment of the materiality of each, if any, to the examination of the above-identified application.

In reviewing the above documents, the Examiner is instructed to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the above-identified application. The copies being submitted with this Information Disclosure Statement are the best copies available at this time.


The identification of any document herein is not intended to be, and should not be understood as being, an admission that each such document, in fact, constitutes "prior art" within the meaning of applicable law.

Applicant respectfully requests that the documents cited herein be made of record in the normal manner and that such documents appear on the printed patent as being considered and made of record.

Respectfully submitted,

Date: January 4, 2006

By:



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**FORM PTO-1449 TO BE FILED WITH
INFORMATION DISCLOSURE STATEMENT**

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.: 183625-3
Serial No.: 10804845
Filing Date: 3/19/2004
Applicant: Robert Harris et al.

INFORMATION
DISCLOSURE STATEMENT
BY APPLICANTS

U.S. PATENTS

| Examiner's Initials | Document No. | Date | Name | Class/Sub-Class |
|---------------------|--------------|------------|-----------|-----------------|
| | 4,473,495 | 09/24/1984 | Patterson | 260/112 R |

U.S. PATENT APPLICATIONS

| Examiner's Initials | Document No. | Date | Name | Class/Sub-Class |
|---------------------|--------------------|------------|---------------|-----------------|
| | US 2002/0090357 A1 | 07/11/2002 | Barrat et al. | 424/93.7 |

FOREIGN DOCUMENTS

| Examiner's | Document No. | Date | Name |
|------------|-------------------|------------|---------------|
| | PCT/IB2004/002124 | 10/26/2005 | Robertson |
| | W0 2004/035084 | 04/29/2004 | Harris et al. |

OTHER DOCUMENTS

1. Banga, J. P. et al., Modulation of Antigen Presentation by Autoreactive B Cell Clones Specific for GAD65 from a type I Diabetic Patient, Clinical and Experimental Immunology, Vol. 135, No. 1, January, 2004, pp. 74-84.

2. Chen Shiow-Ling et al., Responses of NOD Congenic Mice to a Glutamic Acid Decarboxylase-derived Peptide, *Journal of Autoimmunity*, Vol. 7, No. 5, 1994, pp. 635-641.
3. DMCCAD: GAD in Metabolic & Neurologic Disease, http://www.diamyd.com/docs/pdf/GAD_IN_METABOLIC_PD, June, 2003.
4. Patent Abstracts of Japan, Vol. 1997, No. 12, 12/25/97, JP 09 2200092 A.
5. Endl Josef et al., Identification of Naturally Processed T Cell Epitopes from Glutamic Acid Decarboxylase Presented in the Context of HLA-DR Alleles by T Lymphocytes of Recent Onset IDDM Patients, *Journal of Clinical Investigation*, Vol. 99, No. 10, 1997, pp. 2405-2415.
6. Tian Jide et al., T Cell Cross-Reactivity Between Coxsackievirus and Glutamate Decarboxylase is Associated with a Murine Diabetes Susceptibility Allele, *Journal of Experimental Medicine*, Vol. 180, No. 5, 1994, pp. 1979-1984.
7. PCT International Search Report, PCT/IB2005/002135, 08/11/2005.
8. Press Release: Diamyd increases C-peptide levels in diabetes patients with GAD antibodies, online 11/24/2003, http://222.diamyd.com/docs/PressClip.a.spx?PageID=10&LangID=2&ClipID=210&sm+b_b, pp. 1-55.
9. Diamyd: Halvarsrapport for Diamyd Medical AB, online 05/02/2000, pp. 1-5, <http://di.se/Avdelningar/pressreleaseShow.aspx?pressSeqNo=996&pressCp=1&smallscreen=0&>>.

10. Ramiya, V. K. et al., Immunization Therapies in the Prevention of Diabetes, Journal of Autoimmunity, London, GB, Vol. 10, 1997, pages 287-292, XP002918457 abstract.
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15. Elliott, J. F. et al., Immunization with the Larger Isoform of Mouse Glutamic Acid Decarboxylase (GAD67) Prevents Autoimmune Diabetes in NOD Mice, Diabetes, New York, NY, US, Vol. 43, No. 12, 12/01/1994, pp. 1494-1499.
16. Tisch, R. et al., Antigen-specific Mediated Suppression of Beta Cell Autoimmunity by Plasmid DNA Vaccination, Journal of Immunology, The Williams and Wilkins Co., Baltimore, US, Vol. 166, No. 3, 02/01/2001., pp. 2122-2132.

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| Examiner | Date Considered |
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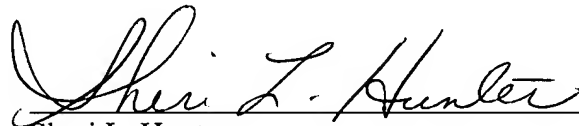
Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

The identification of any document herein is not intended to be, and should not be understood as being, an admission that each such document, in fact, constitutes "prior art" within the meaning of applicable law since, for example, a given document may have a later effective date than at first seems apparent or the document may have an effective date which can be antedated. The "prior art" status of any document is a matter to be resolved during prosecution.

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Sheri L. Hunter